pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 8, 2023	January 8, 2024	*See below

SUBJECT

Prior Authorization of Lipotropics, Other – Pharmacy Services

BY

Sally A. Kozak, Deputy Secretary
Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Lipotropics, Other submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Lipotropics, Other will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Lipotropics, Other to the appropriate managed care organization.

BACKGROUND:

*01-23-44	09-23-43	27-23-34	33-23-41
02-23-32	11-23-32	30-23-35	
03-23-30	14-23-31	31-23-45	
08-23-47	24-23-40	32-23-30	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).
- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 13, 2023, meeting, the P&T Committee recommended revisions to the medical necessity guidelines for Lipotropics, Other to reflect the place in therapy of proprotein convertase subtilisin/kexin type 9 inhibitors and adenosine triphosphate-citrate lyase (ACL) inhibitors and to remove the guideline that an ACL inhibitor is prescribed by or in consultation with an appropriate specialist.

The revisions to the guidelines to determine medical necessity of prescriptions for Lipotropics, Other submitted for prior authorization, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Lipotropics, Other are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Lipotropics, Other) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

I. Requirements for Prior Authorization of Lipotropics, Other

A. Prescriptions That Require Prior Authorization

Prescriptions for Lipotropics, Other that meet any of the following conditions must be prior authorized:

1. A non-preferred Lipotropic, Other. See the Preferred Drug List (PDL) for the list of preferred Lipotropics, Other at: https://papdl.com/preferred-drug-list.

2. A Lipotropic, Other with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Leqvio [inclisiran], Praluent [alirocumab], Repatha [evolocumab]).

4. An adenosine triphosphate-citrate lyase (ACL) inhibitor (e.g., Nexletol [bempedoic acid], Nexlizet [bempedoic acid/ezetimibe]).

5. A microsomal triglyceride transfer protein (MTP) inhibitor (e.g., Juxtapid [lomitapide]).

6. An angiopoietin-like 3 (ANGPTL3) inhibitor (e.g., Evkeeza [evinacumab]).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Lipotropic, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the requested Lipotropic, Other for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. For treatment of a lipid disorder, has documentation of results of a lipid profile within 3 months prior to the request for the Lipotropic, Other; **AND**

6. For a PCSK9 inhibitor, **all** of the following:

    a. Has at least **one** of the following:

        i. A history of clinical atherosclerotic cardiovascular disease (ASCVD),[1]
        ii. A diagnosis of familial hypercholesterolemia in accordance with current consensus guidelines,[2]
        iii. A diagnosis of other severe hypercholesterolemia (baseline [before treatment with any lipid-lowering agent] LDL-C ≥190 mg/dL),

    b. Has a history of **one** of the following:

        i. Failure to achieve goal LDL-C or percentage reduction of LDL-C while adherent to treatment with the maximally tolerated dose of a high-intensity statin for ≥3 months,

        ii. **Both** of the following:

            a) A temporally related intolerance[3] to 2 high-intensity statins that occurred after **both** of the following:

                (i) Modifiable comorbid conditions that may enhance statin intolerance were ruled out and/or addressed by the prescriber as clinically indicated (e.g., hypothyroidism, vitamin D deficiency)

                (ii) All possible drug interactions with statins were addressed by **all** of the following (if clinically appropriate):

                    a. Dose decrease of the interacting non-statin drug,
                    b. Discontinuation of the interacting non-statin drug,
                    c. Change to an alternative statin that has a lower incidence of drug interactions

            b) **One** of the following:

                (i) Therapeutic failure while adherent to treatment for ≥3 consecutive months with the lowest FDA-approved daily dose or alternate-day dosing of any statin
                (ii) A temporally related intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin,

[1] Clinical ASCVD consists of acute coronary syndromes, history of myocardial infarction, stable or unstable angina or coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral artery disease including aortic aneurysm, all of atherosclerotic origin. (American Heart Association 2018 Cholesterol Clinical Practice Guidelines)
[2] e.g., American Heart Association, International Familial Hypercholesterolaemia Foundation, European Atherosclerosis Society, International Atherosclerosis Society
[3] Temporally related intolerance of a statin is defined as the occurrence of symptoms and/or lab abnormalities upon initiation of a statin, resolution of symptoms and/or lab abnormalities upon discontinuation of a statin, and recurrence of symptoms and/or lab abnormalities after rechallenge with the same statin at the same dose.

iii. A contraindication to statins,

c. Has **one** of the following:

i. A history of therapeutic failure of while adherent to treatment with ezetimibe in combination with the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months,
ii. A contraindication or an intolerance to ezetimibe,
iii. An LDL-C that is >25% above goal LDL-C while adherent to treatment with the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months,

d. Is prescribed the requested PCSK9 inhibitor in addition to **one** of the following:

i. For treatment of homozygous familial hypercholesterolemia (HoFH), standard lipid-lowering treatments as recommended by current consensus guidelines[4]
ii. For treatment of all other conditions, the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),

e. If currently using a different PCSK9 inhibitor, will discontinue use of that PCSK9 inhibitor prior to starting the requested PCSK9 inhibitor,

f. For a non-preferred PCSK9 inhibitor, has **one** of the following:

i. A history of therapeutic failure of at least 1 preferred PCSK9 inhibitor approved or medically accepted for the beneficiary's diagnosis
ii. A contraindication or an intolerance to the preferred PCSK9 inhibitors approved or medically accepted for the beneficiary's diagnosis;

AND

7. For an ACL inhibitor, **all** of the following:

a. Has at least **one** of the following:

i. A history of clinical ASCVD,
ii. A diagnosis of familial hypercholesterolemia in accordance with current consensus guidelines,
iii. A diagnosis of other severe hypercholesterolemia (baseline [before treatment with any lipid-lowering agent] LDL-C ≥190 mg/dL),

[4] e.g., American Heart Association/American College of Cardiology, American Association of Clinical Endocrinologists/American College of Endocrinology, American Diabetes Association, National Lipid Association, European Society of Cardiology/European Atherosclerosis Society, International Familial Hypercholesterolaemia Foundation, International Atherosclerosis Society

b. Has a history of **one** of the following:

   i. Failure to achieve goal LDL-C or percentage reduction of LDL-C while adherent to treatment with the maximally tolerated dose of a high-intensity statin for ≥3 months,

   ii. **Both** of the following:

      a) A temporally related intolerance to 2 high-intensity statins that occurred after **both** of the following:

         (i) Modifiable comorbid conditions that may enhance statin intolerance were ruled out and/or addressed by the prescriber as clinically indicated (e.g., hypothyroidism, vitamin D deficiency)

         (ii) All possible drug interactions with statins were addressed by **all** of the following (if clinically appropriate):

            a. Dose decrease of the interacting non-statin drug,
            b. Discontinuation of the interacting non-statin drug,
            c. Change to an alternative statin that has a lower incidence of drug interactions

      b) **One** of the following:

         (i) Therapeutic failure while adherent to treatment for ≥3 consecutive months with the lowest FDA-approved daily dose or alternate-day dosing of any statin
         (ii) A temporally related intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin,

   iii. A contraindication to statins,

c. Has **one** of the following:

   i. A history of therapeutic failure of while adherent to treatment with ezetimibe in combination with the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months
   ii. A contraindication or an intolerance to ezetimibe,

d. Is prescribed the requested ACL inhibitor in addition to the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),

e. If currently taking simvastatin or pravastatin, will not be using the requested ACL inhibitor concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily;

AND

8. For an ANGPTL3 inhibitor or MTP inhibitor, **all** of the following:

    a. Is prescribed the requested medication by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders,

    b. For treatment of HoFH, has a diagnosis of HoFH in accordance with current consensus guidelines,

    c. **One** of the following:

        i. Has a history of therapeutic failure of or a contraindication or an intolerance to PCSK9 inhibitors
        ii. Is homozygous for LDL receptor (LDLR)-negative mutations (i.e., has LDLR-negative mutations in both alleles) associated with LDLR activity below 2%,

    d. Is prescribed the requested medication in addition to standard lipid-lowering treatments as recommended by current consensus guidelines;

    AND

9. For icosapent ethyl, **all** of the following:

    a. **One** of the following:

        i. Has a history of clinical ASCVD,

        ii. **Both** of the following:

            a) Has diabetes mellitus
            b) Has 2 additional ASCVD risk factors (e.g., age ≥50 years, cigarette smoking, hypertension, HDL-C ≤40 mg/dL for males or ≤50 mg/dL for females, hs-CRP >3.00 mg/L, CrCl <60 mL/min, retinopathy, micro- or macroalbuminuria, ABI <0.9]),

        iii. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis,

    b. Has fasting triglycerides ≥150 mg/dL,

    c. Has **one** of the following:

        i. A history of therapeutic failure of while adherent to treatment with maximally

tolerated doses of 2 different statins for ≥3 consecutive months each,
ii. A history of statin intolerance after modifiable risk factors have been addressed,
iii. A contraindication to statins;

AND

10. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis; **AND**

11. If a prescription for a Lipotropic, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

    NOTE: If the beneficiary does not meet the clinical review guidelines but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR LIPOTROPICS, OTHER: The determination of medical necessity of a request for renewal of a prior authorization for a Lipotropic, Other that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response demonstrated by lab test results, if appropriate for the diagnosis, since starting the requested medication (e.g., decreased LDL-C, decreased triglycerides, etc.); **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Does not have a contraindication to the prescribed medication; **AND**

4. For a PCSK9 inhibitor, is using the requested PCSK9 inhibitor in addition to **one** of the following:

    a. For treatment of HoFH, standard lipid-lowering treatments as recommended by current consensus guidelines[5]
    b. For treatment of all other conditions, the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate);

    AND

[5] e.g., American Heart Association/American College of Cardiology, American Association of Clinical Endocrinologists/American College of Endocrinology, American Diabetes Association, National Lipid Association, European Society of Cardiology/European Atherosclerosis Society, International Familial Hypercholesterolaemia Foundation, International Atherosclerosis Society

5. For an ACL inhibitor, **both** of the following:

   a. Is using the requested ACL inhibitor in addition to the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate)
   b. If currently taking simvastatin or pravastatin, is not using the requested ACL inhibitor concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily;

   AND

6. For an ANGPTL3 inhibitor or MTP inhibitor, **both** of the following:

   a. Is prescribed the requested medication by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders
   b. Is using the requested medication in addition to standard lipid-lowering treatments as recommended by current consensus guidelines;

   AND

7. For icosapent ethyl, experienced a decrease in fasting triglycerides since starting icosapent ethyl; **AND**

8. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis; **AND**

9. If a prescription for a Lipotropic, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Lipotropic, Other. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Lipotropics, Other will be approved as follows:

1. For a PCSK9 inhibitor:

   a. Initial requests will be approved for up to 3 months.
   b. Renewal requests will be approved for up to 12 months.

2. For an ACL inhibitor:

   a. Initial requests will be approved for up to 3 months.
   b. Renewal requests will be approved for up to 12 months.

3. For all other Lipotropics, Other:

   a. Initial requests will be approved for up to 6 months.
   b. Renewal requests will be approved for up to 12 months.

E. References

1. Praluent (alirocumab) package insert. Bridgewater, NJ: sanofi-aventis U.S. LLC; April 2019.
2. Repatha (evolocumab) package insert. Thousand Oaks, CA: Amgen Inc. February 2019.
3. Juxtapid (lomitapide) package insert. Cambridge, MA: Aegerion Pharmaceuticals, Inc. July 2017.
4. Nexletol (bempedoic acid) package insert. Ann Arbor, MI: Esperion Therapeutics, Inc. February 2020.
5. Nexlizet (bempedoic acid and ezetimibe) package insert. Ann Arbor, MI: Esperion Therapeutics, Inc. February 2020.
6. Evkeeza (evinacumab-dgnb) package insert. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. February 2021.
7. Leqvio (inclisiran) package insert. East Hanover, NJ: Novartis Pharmaceuticals Corporation. December 2021.
8. Cholesterol Treatment Trialists' (CTT) Collaboration. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170000 participants in 26 randomised trials. Lancet. 2010;376(9753):1670-1681.
9. Goff DC Jr, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014;129(suppl 2):S49-S73.
10. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. Endocri Pract. 2017;23(Suppl. 2):1-87.
11. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019;139:e1082-e1143.
12. The Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS). 2019 ESC/EAS guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk. Eur Heart J. 2019;00:1-78.
13. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 guideline for the prevention of stroke in patients with stroke and transient ischemic attack: A guideline from the American Heart Association/American Stroke Association. Stroke. 2021;52:e364-e467.

14. Visseren JLF, Mach F, Smulders VM, et al. 2021 ESC guidelines on cardiovascular disease prevention in clinical practice. Eur Heart J. 2021;42:3227-3337.
15. Virani SS, Morris PB, Agarwala A, et al. 2021 ACC excerpt consensus decision pathway on the management of ASCVD risk reduction in patients with persistent hypertriglyceridemia: A report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2021;78(9):960-993.
16. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC expert consensus decision pathway role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: A report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2022. https://doi.org/10.1016/j.jacc.2022.07.006.
17. Rosenson RS, Hayward RA, Lopez-Sendon J. Management of low density lipoprotein cholesterol (LDL-C) in the secondary prevention of cardiovascular disease. In: UpToDate [internet database]. Freeman MW, Cannon CP, Parikh N, eds. Waltham, MA: UpToDate Inc. Updated April 1, 2022. Accessed April 18, 2022.
18. Rosenson RS, Eckel RH. Hypertriglyceridemia in adults: Management. In: UpToDate [internet database]. Freeman MW, Parikh N, Givens J, eds. Waltham, MA: UpToDate Inc. Updated March 4, 2022. Accessed July 6, 2022.

Inherited Dyslipidemias

19. Watts GF, Gidding S, Wierzbicki AS, et al. Integrated guidance on the care of familial hypercholesterolaemia from the International FH Foundation. Cardiology Faculty Papers. 2014; Paper 42. http://jdc.jefferson.edu/cardiologyfp/42.
20. Gidding SS, Champagne MA, de Ferranti SD, et al. The agenda for familial hypercholesterolemia – a scientific statement from the American Heart Association. Circulation. 2015;132:2167-2192.
21. Santos RD, Gidding SS, Hegele RA, et al. Defining severe familial hypercholesterolemia and the implications for clinical management: a consensus statement form the International Atherosclerosis Society Severe Familial Hypercholesterolemia Panel. Lancet Diabetes-Endocrinol. 2016;4(10):850-861.
22. Wiegman A, Gidding SS, Watts GF, et al. Familial hypercholesterolaemia in children and adolescents: gaining decades of life by optimizing detection and treatment. Eur Heart J. 2015;36(36):2425-2437.
23. France M, Rees A, Datta D, et al. HEART UK statement on the management of homozygous familial hypercholesterolaemia in the United Kingdom. Atherosclerosis. 2016;255:128-139.
24. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014;35(32):2146-2157.
25. Raal FJ, Hovingh GK, Catapano AL. Familial hypercholesterolemia treatments: guidelines and new therapies. Atherosclerosis. 2018;277:483-492.
26. Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: treatment. In: UpToDate [internet database]. Freeman MW, Parikh N, eds. Waltham, MA: UpToDate Inc. Updated September 14, 2020. Accessed April 18, 2022.
27. Rosenson RS, Durrington P. Inherited disorders of LDL-cholesterol metabolism other than familial hypercholesterolemia. In: UpToDate [internet database]. Freeman MW, Cosentino F, Parikh N, eds. Waltham, MA: UpToDate Inc. Updated July 1, 2020. Accessed April 18, 2022.

Non-Statin Medications

28. Landmesser U, Chapman MJ, Stock JK, et al. 2017 update of ESC/EAS Task Force on practical clinical guidance for proprotein convertase subtilisin/kexin type 9 inhibition in patients with atherosclerotic cardiovascular disease or in familial hypercholesterolaemia. Eur Heart J. 2018;39(14):1131-1143.
29. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 focused update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Decision Pathways. J Am Coll Cardiol. 2017;70(14):1785-1822.
30. Orringer CE, Jacobson TA, Saseen JJ, et al. Update on the use of PCSK9 inhibitors in adults: recommendations from an Expert Panel of the National Lipid Association. J Clin Lipidol. 2017;11:880-890.
31. Banach M, Penson PE, Farnier M, et al. Bempedoic acid in the management of lipid disorders and cardiovascular risk. 2023 position paper of the International Lipid Expert Panel (ILEP). Prog Cardiovasc Dis. 2023 Mar 7;S0033-0620(23)00026-9.

Statin Intolerance

32. Rosenson RS, Baker SK, Jacobson TA, et al. An assessment by the Statin Muscle Safety Task Force: 2014 update. J Clin Lipidol. 2014;8:S58-S71.
33. Bays H, Cohen DE, Chalasani N, Harrison SA. An assessment by the Statin Liver Safety Task Force: 2014 update. J Clin Lipidol. 2014;8:S47-S57.
34. Guyton JR, Bays HE, Grundy SM, Jacobson TA. An assessment by the Statin Intolerance Panel: 2014 update. J Clin Lipidol. 2014;8:S72-S81.
35. Stroes ES, Thompson PD, Corsini A, et al. Statin-associated muscle symptoms: impact on statin therapy – European Atherosclerosis Society Consensus Panel state on assessment, aetiology and management. Eur Heart J. 2015;36:1012-1022.
36. Banach M, Rizzo M, Toth P, et al. Statin intolerance – an attempt at a unified definition. Position paper from an International Lipid Expert Panel. Arch Med Sci. 2015;11(1):1-23.
37. Mancini GBJ, Baker S, Bergeron J, et al. Diagnosis, prevention, and management of statin adverse effects and intolerance: Canadian Consensus Working Group update (2016). Can J Cardiol. 2016;32:S35-S65.
38. Newman CB, Preiss D, Tobert JA, et al. Statin safety and associated adverse events: A scientific statement from the American Heart Association. Arterioscler Thromb Vasc Biol. 2019;39:e38-e81.
39. Cheeley MK, Saseen JJ, Agarwala A, et al. NLA scientific statement on statin intolerance: A new definition and key considerations for ASCVD risk reduction in the statin intolerant patient. J Clin Lipidol. 2022. doi: https://doi.org/10.1016/j.jacl.2022.05.068.
40. Rosenson RS, Baker SK. Statin myopathy. In: UpToDate [internet database]. Freeman MW, Rind DM, eds. Waltham, MA: UpToDate. Updated July 10, 2015.
41. Rosenson RS, Baker SK. Statin muscle-related adverse events. In: UpToDate [internet database]. Freeman MW, Givens J, eds. Waltham, MA: UpToDate Inc. Updated February 25, 2019. Accessed August 9, 2019.